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Bringing New Horizons to Therapy

EDAP Announces Approval to Initiate Randomized Clinical Trial Evaluating Focal One® as a Potential Treatment for Rectal Deep Infiltrating Endometriosis

November 30, 2022

Study to begin enrolling patients in Q2 2023

Endometriosis represents significant expansion opportunity for Focal One

LYON, France, November 30, 2022 -- EDAP TMS SA (Nasdaq: EDAP) ("the Company"), the global leader in robotic therapeutic ultrasound, today announced that the Company has received approval from French authorities to initiate a Phase 3 randomized, controlled clinical trial evaluating Focal One high intensity focused ultrasound (HIFU) as a potential treatment for rectal deep infiltrating endometriosis.

Marc Oczachowski, Chairman and Chief Executive Officer of EDAP TMS, stated, "This is great news and a notable milestone for our Focal One HIFU endometriosis program. This level 1 study – the most rigorous trial design - is a multi-center, double blind, randomized, controlled clinical trial. This study will allow us to continue to build strong clinical evidence demonstrating the efficacy and added value of HIFU for patients suffering from this painful and debilitating condition.

"The study will enroll 60 subjects across eight centers in France, with 30 subjects randomized to each group. The primary efficacy endpoint is acute pelvic pain three months post procedure. At the conclusion of the study, subjects in the other group will be offered HIFU treatment. We look forward to initiating enrollment in this important study in the second quarter of next year."

This will be EDAP's third study evaluating Focal One HIFU for endometriosis. The Company recently completed a Phase 2 study evaluating HIFU as a potential treatment for deep infiltrating endometriosis. The Phase 2 study enrolled 60 subjects across four centers in France. Data from this study is currently being analyzed with the anticipation of the final results on safety and efficacy being presented at a medical meeting in early 2023.

About EDAP TMS SA

A recognized leader in the global therapeutic ultrasound market. EDAP TMS develops, manufactures, promotes and distributes worldwide minimally invasive medical devices for various pathologies using ultrasound technology. By combining the latest technologies in imaging and treatment modalities in its complete range of Robotic HIFU devices, EDAP TMS introduced the Focal One® in Europe and in the U.S. as an answer to all requirements for ideal prostate tissue ablation. With the addition of the ExactVu™ Micro-Ultrasound device, EDAP TMS is now the only company offering a complete solution from diagnostics to focal treatment of Prostate Cancer. EDAP TMS also produces and distributes other medical equipment including the Sonolith® i-move lithotripter and lasers for the treatment of urinary tract stones using extra-corporeal shockwave lithotripsy (ESWL). For more information on the Company, please visit <http://www.edap-tms.com>, us.hifu-prostate.com and www.focalone.com.

Forward-Looking Statements

In addition to historical information, this press release contains forward-looking statements. Such statements are based on management's current expectations and are subject to a number of risks and uncertainties, including matters not yet known to us or not currently considered material by us, and there can be no assurance that anticipated events will occur or that the objectives set out will actually be achieved. Important factors that could cause actual results to differ materially from the results anticipated in the forward-looking statements include, among others, the clinical status and market acceptance of our HIFU devices and the continued market potential for our lithotripsy device, as well as the length and severity of the recent COVID-19 outbreak, including its impacts across our businesses on demand for our devices and services. Factors that may cause such a difference also may include, but are not limited to, those described in the Company's filings with the Securities and Exchange Commission and in particular, in the sections "Cautionary Statement on Forward-Looking Information" and "Risk Factors" in the Company's Annual Report on Form 20-F.

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